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PATENT
Customer No. 22,852
Attorney Docket No. 09797.0002-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
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Peiyuan WANG et al.) Group Art Unit: 1617
)
Serial No.: 10/632,997) Examiner: Carlic K. Huynh
)
Filed: August 1, 2003) Confirmation No.: 8974
)
For: COMPOUNDS WITH THE)
BICYCLO[4.2.1] NONANE)
SYSTEM FOR THE TREATMENT)
OF FLAVIVIRIDAE INFECTIONS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In response to the Restriction Requirement mailed November 30, 2006, the Examiner required restriction under 35 U.S.C. § 121 between the following Groups of allegedly distinct inventions:

- I. Claims 1-6 and 10-12, allegedly drawn to a method of treatment of an HCV infection comprising administering a compound of formula (I), where each of R^1 , R^3 , R^6 , and R^7 is independently any group other than heterocycle or heteroaryl, R^2 is any group other than $-NR'$ or $-CR'_2$, and W is assumed to be O by the Examiner, classified in class 514, subclass 221.
- II. Claims 1-6 and 10-12, allegedly drawn to a method of treatment of an HCV infection comprising administering a compound of formula (I), where each of R^1 ,

R^3 , R^6 , and R^7 is independently heterocycle or heteroaryl, R^2 is any group other than $-NR'$ or $-CR'_2$, and W is assumed to be O by the Examiner, classified in class 514, subclass 221.

- III. Claims 1-6 and 10-12, allegedly drawn to a method of treatment of an HCV infection comprising administering a compound of formula (I), where each of R^1 , R^3 , R^6 , and R^7 is independently any group other than heterocycle or heteroaryl, R^2 is $-NR'$ such that R^1 or R^3 can come together with $-NR'$ to form a 5-7 membered ring, and W is assumed to be O by the Examiner, classified in class 514, subclass 221.
- IV. Claims 1-6 and 10-12, allegedly drawn to a method of treatment of an HCV infection comprising administering a compound of formula (I), where each of R^1 , R^3 , R^6 , and R^7 is independently any group other than heterocycle or heteroaryl, R^2 is $-CR'_2$ such that R^1 or R^3 can come together with $-CR'_2$ to form a 5-7 membered ring, and W is assumed to be O by the Examiner, classified in class 514, subclass 221.
- V. Claims 1-6 and 10-12, allegedly drawn to a method of treatment of an HCV infection comprising administering a compound of formula (I), where each of R^1 , R^3 , R^6 , and R^7 is independently any group other than heterocycle or heteroaryl, R^2 is $-CR'_2$ such that R^1 or R^3 can come together with $-CR'_2$ to form a bicyclic ring, and W is assumed to be O by the Examiner, classified in class 514, subclass 221.
- VI. Claims 1-6 and 10-12, allegedly drawn to a method of treatment of an HCV infection comprising administering a compound of formula (I), where each of R^1 ,

R^3 , R^6 , and R^7 is independently heterocycle or heteroaryl, R^2 is $-NR'$ such that R^1 or R^3 can come together with $-NR'$ to form a 5-7 membered ring, and W is assumed to be O by the Examiner, classified in class 514, subclass 221.

- VII. Claims 1-6 and 10-12, allegedly drawn to a method of treatment of an HCV infection comprising administering a compound of formula (I), where each of R^1 , R^3 , R^6 , and R^7 is independently heterocycle or heteroaryl, R^2 is $-CR'_2$ such that R^1 or R^3 can come together with $-CR'_2$ to form a 5-7 membered ring, and W is assumed to be O by the Examiner, classified in class 514, subclass 221.
- VIII. Claims 1-12, allegedly drawn to a method of treatment of an HCV infection comprising administering a compound of formula (I), where each of R^1 , R^3 , R^6 , and R^7 is independently heterocycle or heteroaryl, R^2 is $-CR'_2$ such that R^1 or R^3 can come together with $-CR'_2$ to form a bicyclic ring, and W is assumed to be O by the Examiner, classified in class 514, subclass 221.
- IX. Claims 13-18 and 22-24, allegedly drawn to a compound of formula (I), where each of R^1 , R^3 , R^6 , and R^7 is independently any group other than heterocycle or heteroaryl, R^2 is any group other than $-NR'$ or $-CR'_2$, and W is assumed to be O by the Examiner, classified in class 514, subclass 221.
- X. Claims 13-18 and 22-24, allegedly drawn to a compound of formula (I), where each of R^1 , R^3 , R^6 , and R^7 is independently heterocycle or heteroaryl, R^2 is any group other than $-NR'$ or $-CR'_2$, and W is assumed to be O by the Examiner, classified in class 514, subclass 221.
- XI. Claims 13-18 and 22-24, allegedly drawn to a compound of formula (I), where each of R^1 , R^3 , R^6 , and R^7 is independently any group other than heterocycle or

heteroaryl, R^2 is $-NR'$ such that R^1 or R^3 can come together with $-NR'$ to form a 5-7 membered ring, and W is assumed to be O by the Examiner, classified in class 514, subclass 221.

- XII. Claims 13-18 and 22-24, allegedly drawn to a compound of formula (I), where each of R^1 , R^3 , R^6 , and R^7 is independently any group other than heterocycle or heteroaryl, R^2 is $-CR'_2$ such that R^1 or R^3 can come together with $-CR'_2$ to form a 5-7 membered ring, and W is assumed to be O by the Examiner, classified in class 514, subclass 221.
- XIII. Claims 13-24, allegedly drawn to a compound of formula (I), where each of R^1 , R^3 , R^6 , and R^7 is independently any group other than heterocycle or heteroaryl, R^2 is $-CR'_2$ such that R^1 or R^3 can come together with $-CR'_2$ to form a bicyclic ring, and W is assumed to be O by the Examiner, classified in class 514, subclass 221.
- XIV. Claims 13-18 and 22-24, allegedly drawn to a compound of formula (I), where each of R^1 , R^3 , R^6 , and R^7 is independently heterocycle or heteroaryl, R^2 is $-NR'$ such that R^1 or R^3 can come together with $-NR'$ to form a 5-7 membered ring, and W is assumed to be O by the Examiner, classified in class 514, subclass 221.
- XV. Claims 13-18 and 22-24, allegedly drawn to a compound of formula (I), where each of R^1 , R^3 , R^6 , and R^7 is independently heterocycle or heteroaryl, R^2 is $-CR'_2$ such that R^1 or R^3 can come together with $-CR'_2$ to form a 5-7 membered ring, and W is assumed to be O by the Examiner, classified in class 514, subclass 221.

XVI. Claims 13-24, allegedly drawn to a compound of formula (I), where each of R^1 , R^3 , R^6 , and R^7 is independently heterocycle or heteroaryl, R^2 is $-CR'_2$ such that R^1 or R^3 can come together with $-CR'_2$ to form a bicyclic ring, and W is assumed to be O by the Examiner, classified in class 514, subclass 221.

In response to the restriction requirement, Applicants provisionally elect, with traverse, the subject matter of Group XVI. The elected invention is believed to read on claims 13-24.

The Examiner also requires that Applicants elect a single disclosed species of formula (I) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Restriction Requirement at 7. Applicants elect with traverse claims drawn to a compound of formula 1(J). The elected species is believed to read on claims 13-18 and 20-24.

The Examiner has withdrawn a Restriction Requirement mailed on October 2, 2006. Applicants have since received two new Restriction and/or Election Requirements, one mailed November 30, 2006, and one mailed December 4, 2006, which appear to be identical. Applicants have used the date of the first restriction requirement, November 30, 2006, as the date of the Office communication. By virtue of the facts that December 30, 2006, was a Saturday and that the government was closed for New Years day on Monday, January 1, 2007, and on Tuesday, January 2, 2007, for President Ford's funeral, this response is timely filed.

In the Restriction Requirement mailed November 30, 2006, the Examiner alleges that Groups [I-VIII] are unrelated since they involve methods of treating HCV with structurally unrelated compounds. Restriction Requirement at 5. The Examiner

likewise alleges that Groups [IX-XVI] are unrelated since they too relate to structurally different compounds and/or compositions. Restriction Requirement at 6. According to the Examiner, Groups [IX-XVI] and [I-VIII] are related as product and process of use. *Id.* The Examiner acknowledges that searches of Groups [I-VIII] and [IX-XVI] may be overlapping, but then states that no reason exists “to believe that the searches will be coextensive.” *Id.*

While Section 121 gives the U.S.P.T.O. authority to restrict between claims of an application reciting one or more independent and distinct inventions, it does not provide authority to reject a claim on that basis, in effect requiring an applicant to break up the claim and present it in several applications. *In re Weber*, 580 F.2d 455, 458-59 (Fed. Cir. 1978). The *Weber* court held that an Examiner cannot require an applicant to divide up the embodiments of a single Markush group. *Id.* at 458. Contrary to *Weber*, the Examiner here subdivides many of Applicants’ claims and breaks them up into multiple groups while ignoring the commonality and considerable overlap found within those claims.

The Examiner separates Applicants’ method of treatment claim 1 into Groups [I-VIII] and the corresponding compound claim 13 into Groups [IX-XVI]. Applicants respectfully point out to the Examiner that all compounds of formula (I) share a common core and are properly members of a single Markush claim. Compounds of formula (I) where R^1 , R^3 , R^6 , or R^7 are heterocycle or heteroaryl as opposed to non-heterocycle or heteroaryl differ only in that they contain different bases as part of the nucleoside-derived bicyclo[4.2.1]nonane system. Similarly, the only differences in compounds of formula (I) where R^2 is $-NR'$ such that R^1 or R^3 can come together with $-NR'$ to form a

5-7 membered ring, R^2 is $-CR'_2$ such that R^1 or R^3 can come together with $-CR'_2$ to form a 5-7 membered ring, or R^2 is $-CR'_2$ such that R^1 or R^3 can come together with $-CR'_2$ to form a bicyclic ring, is that the resulting bicyclo[4.2.1]nonane compounds would contain different bases. In addition, Applicants respectfully submit that R^6 and R^7 are not even identified on the core structural drawing of a compound of the formula (I). R^6 and R^7 further define two specific R^4 , R^4' , R^5 , or R^5' species, CH_2OR^6 and NR^6R^7 , on the sugar-derived moiety of the bicyclo[4.2.1]nonane. Applicants should not be penalized for clarifying the genus of claim 1 or claim 13 by providing both formulas with and without specific bases and sugar-derived substituents.

Moreover, M.P.E.P. § 803 states that two requirements must be met before a proper Restriction Requirement may be made. These two requirements are: "[t]he inventions must be independent . . . or distinct as claimed; and there must be a serious burden on the Examiner if restriction is required" (Emphasis added). The Examiner fails to establish the second requirement set forth in M.P.E.P. § 803, that a serious burden on the Examiner exists if restriction is not required among Applicants' claims. M.P.E.P. § 808.02 lays out the requirements for establishing a serious burden. An examiner must show that the search and examination would impose a serious burden on the Office because the alleged inventions have a separate classification, a separate status in the art, or a different field of search. *Id.* Here, the Examiner only contends that the searches of Groups [I-VIII] and [IX-XVI] may not be coextensive while acknowledging that the searches may be overlapping. Restriction Requirement at 6. The Examiner does not explain why a search within the method of treatment claims, Groups [I-VIII], or within the compound or compositions claims, Groups [IX-XVI], would

impose a serious burden. In fact, all of the Examiner-identified groups are within the same field of search and classification. Therefore, the Examiner has failed to establish a serious burden if restriction is not required between the claims in Groups [I-VIII] or [IX-XVI].

Accordingly, Applicants contend that, at the very least:

- 1) Groups I-VIII should be combined into a single group; and
- 2) Groups IX-XVI should be combined into a single group.

Further searches of the compounds of formula (I) with different bases or sugar-derived substituents should not place an undue burden on the Examiner since the Examiner acknowledges that all of the compounds are found in the same subclass, subclass 221. Restriction Requirement at 2-5. Nor should the search of these nucleoside-derived bicyclo[4.2.1]nonanes containing a narrow group of bases and sugar-derived substituents provide cause for the Examiner to separate Applicants' claims 1 and 13, both a single Markush claim, into 8 separate groups each.

For at least these reasons, and in order to avoid unnecessary delay and expense to Applicants and duplicative examination by the Office, Applicants respectfully request that the Restriction Requirement be reconsidered and revised as proposed.


Applicants request that the Examiner contact their representative, William Strauss, at 202-408-4185 should the need arise.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: January 3, 2007

By: 
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